

Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application:

Claim 1 (original): A pharmaceutical composition for the oral administration of an active agent having low water solubility, wherein

- a) the active agent is dispersed in an aqueous formulation base; and
- b) the solubilizing agent is suitable for the formation of an aqueous dispersion of nanoparticles;

which is characterized in that the solubilizing agent is a pharmaceutically acceptable polymer which is resistant to gastric juices and soluble in intestinal juices.

Claim 2 (original): A pharmaceutical composition according to claim 1, wherein the polymer, which is resistant to gastric juices and soluble in intestinal juices is a copolymer from monomers selected from the group consisting of methacrylic acid, methacrylic acid esters, acrylic acid and acrylic acid esters.

Claim 3 (currently amended): A pharmaceutical composition according to claim 1, wherein the said pharmaceutically acceptable polymer, which is resistant to gastric juices and soluble in intestinal juices, is a pharmaceutically acceptable cellulose derivative selected from the group consisting of hydroxypropyl methyl cellulose acetate succinate (HPMCAS), ~~hydroxypropylmethylcellulose-phthalate~~ hydroxypropyl methyl cellulose phthalate (HPMCP), ~~celluloseacetate-phthalate~~ cellulose acetate phthalate (CAP), and ~~celluloseacetatetrimellitate~~ cellulose acetate trimellitate (CAT).

Claim 4 (currently amended): A pharmaceutical composition according to claim 2, wherein said pharmaceutically acceptable the polymer is a 1:1-up to 1:2-copolymer from monomers selected from the group consisting of methacrylic acid and methacrylic acid lower alkyl esters.

Claim 5 (original): A pharmaceutical composition according to claim 4, wherein the copolymer is a 1:1-up to 1:2-copolymer of methacrylic acid and methacrylic acid methyl ester.

Claim 6 (original): A pharmaceutical composition according to claim 2, wherein the copolymer is a 1:1-copolymer of methacrylic acid and acrylic acid ethyl ester.

Claim 7 (cancelled).

Claim 8 (original): A pharmaceutical composition according to claim 1, wherein the formulation base contains water soluble additives suitable for incorporation in a dosage form intended for oral administration.

Claims 9 to 11 (cancelled).

Claim 12 (new): A pharmaceutical composition for the oral administration of an active agent having low water solubility comprising nanoparticles of said active agent in a polymeric matrix, wherein said polymeric matrix comprises a pharmaceutically acceptable polymer, said pharmaceutically acceptable polymer being resistant to gastric juices and being soluble in intestinal juices.

Claim 13 (new): A pharmaceutical composition according to claim 12, wherein said pharmaceutically acceptable polymer allows the release of said active agent from said nanoparticles in said intestinal juices having a slightly basic pH.

Claim 14 (new): A pharmaceutical composition according to claim 12, wherein said pharmaceutically acceptable polymer allows the release of said active agent from said nanoparticles in said intestinal juices having a neutral pH.

Claim 15 (new): A pharmaceutical composition according to claim 12, wherein said pharmaceutically acceptable polymer is a copolymer selected from the group consisting of (a) methacrylic acid or acrylic acid and (b) methyl or ethyl esters of acrylic or methacrylic acid monomers.

Claim 16 (new): A pharmaceutical composition according to claim 15, wherein said copolymer is a 1:1-copolymer selected from the group consisting of (a) methacrylic acid and (b) methyl or ethyl esters of acrylic or methacrylic acid monomers.

Claim 17 (new): A pharmaceutical composition according to claim 15, wherein said copolymer is a 1:2-copolymer selected from the group consisting of (a) methacrylic acid and (b) methyl or ethyl esters of acrylic or methacrylic acid monomers.

Claim 18 (new): A pharmaceutical composition according to claim 15, wherein said copolymer is a 1:1-copolymer of (a) methacrylic acid and (b) methacrylic acid methyl ester.

Claim 19 (new): A pharmaceutical composition according to claim 15, wherein said copolymer is a 1:2-copolymer of (a) methacrylic acid and (b) methacrylic acid methyl ester.

Claim 20 (new): A pharmaceutical composition according to claim 15, wherein said copolymer is a 1:1-copolymer of (a) methacrylic acid and (b) acrylic acid ethyl ester.

Claim 21 (new): A pharmaceutical composition according to Claim 1, wherein said pharmaceutically acceptable polymer is polyvinyl acetate phthalate (PVAP).

Claim 22 (new): A pharmaceutical composition according to Claim 12, wherein said pharmaceutically acceptable polymer is polyvinyl acetate phthalate (PVAP).

Claim 23 (new): A pharmaceutical composition according to Claim 1, wherein said nanoparticles are nanospheres.

Claim 24 (new): A pharmaceutical composition according to Claim 12, wherein said nanoparticles are nanospheres.

Claim 25 (new): A pharmaceutical composition according to Claim 1, wherein said active agent has a water solubility of less than 200 mg/1000 ml.

Claim 26 (new): A pharmaceutical composition according to Claim 12, wherein said active agent has a water solubility of less than 200 mg/1000 ml.

Claim 27 (new): A process for preparing a pharmaceutical composition for oral administration of an active agent having low water solubility comprising the steps of:

- a) preparing an aqueous gel comprising a hydrophilic polymer;
- b) preparing a solution of an organic solvent comprising said active agent and a pharmaceutically acceptable polymer, wherein said pharmaceutically acceptable polymer is resistant to gastric juices and soluble in intestinal juices;
- c) combining said gel from step a with said solution of step b; and
- d) adding pure water to said combination of step c to form a homogenous aqueous dispersion of nanoparticles.

Claim 28 (new): The process according to claim 27, wherein said aqueous gel further comprises a water soluble salt.

Claim 29 (new): The process according to claim 27, wherein said hydrophilic polymer is polyvinyl alcohol.

Claim 30 (new): The process according to claim 27, further comprising the step of lyophilizing said homogenous aqueous dispersion of nanoparticles to a lyophilizate.

Claim 31 (new): A pharmaceutical composition obtained by said process of claim 27.